

Appl. No. 10/701,498
Amendment dated: June 17, 2005
Reply to OA of: December 17, 2004

REMARKS

Applicants affirm the election of the Group I invention including claims 27-33. Accordingly, claims 34-38 have been canceled without prejudice or disclaimer and reserve the right to file a further application to any canceled subject matter.

Applicants have amended the specification and claims to more particularly define the invention taking into consideration the outstanding Official Action. The specification has been amended at page 12 to add the subheading "Brief Description of the Drawings" and a description of Figure 5 as required in the Official Action. Therefore any objection to the specification should be withdrawn in view of the further amendment to the claims.

As part of the Official Action, the Examiner's provides a claim interpretation with respect to claim 27 as a compound claim notwithstanding the recitation in the claim that it is a composition. Accordingly, Applicants have amended originally presented composition claim 27 to recite the presence of a carrier in view of the Examiner's comments in the Official Action. The claim composition claims now explicitly recite the presence of a carrier. Claim 27 now recites that the composition contains at least one pharmaceutically acceptable carrier or diluent (from the passage bridging pages 2 and 3 of the specification). Applicants most respectfully submit that all the claims now present in the application are in full compliance with 35 U.S.C. §112 and are clearly patentable over the references of record.

The rejection of claims 27-33 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been carefully considered but is most respectfully traversed.

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It is urged in the Official Action that the proviso at the end of claim 27 is confusing as to its meaning and claims 32 and 33 do not conform to MPEP 608.01(m) since each claim must end with a period.

Applicants note that this proviso was incorporated into the parent application at the explicit request of the Examiner in that case and it would seem that this requirement should be given full faith and credit. The proviso is there to ensure no accidental anticipation by the presence of very small quantities of the 4-hydroxy compound in commercial preparations of OPB. The proviso thus indicates that the 4-OH compound is not claimed when in admixture with an overwhelmingly larger quantity of non 4-hydroxylated compound. This situation is clearly described on the first few pages of the specification as filed and Applicants believe that having read this section, the skilled worker would be clear as to the meaning of the proviso, as was the Examiner in the parent case.

Applicants have added the punctuation in claims 32 and 33 thereby obviating this aspect of the rejection. Accordingly, Applicants most respectfully request that this rejection be withdrawn.

The rejections of claims 27-31 under 35 U.S.C. §102(b) as being anticipated by Adembri et al., Franchi, Facchini et al., Eiden et al., Negrevergue, Woodruff et al., Eiden et al., Giraldi et al., Alexander et al., Rahtz et al., or Clopath et al. have been carefully considered but are most respectfully traversed.

The Examiner states that each of the above cited references disclose at least one product that is embraced by the instant claims.

However, this appears to be based on the Examiner's interpretation of the composition claims as compound claims and has ignored the limitation of the present claims to "pharmaceutical compositions." By explicitly introducing the further restriction that the composition should contain at least one pharmaceutically acceptable carrier or diluent from the passage bridging pages 2 and 3, Applicants believe most of the

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rejections of anticipation are removed since only Eiden, Negrevergue and Vidal relate to pharmaceutical applications in which compositions of relevant compounds in a pharmaceutical carrier can be implied.

The remaining questions of anticipation are also addressed by the amendment of claim 27. Specifically, X₁ is restricted to oxygen, thereby distancing the claims from the disclosed thio compounds and R₁ is restricted to hydrogen, or an acryl group with up to six carbons (from page 4, lines 2-5), thereby distancing the claims for accidental anticipation by the various sugar derivatives. In view of these amendments, as fully supported by Applicants' specification as originally filed, applicants believe that claim 27, and therefore the claims dependent thereon are not anticipated by any cited document.

Applicants also wish to direct the Examiner's attention to MPEP § 2131 which states that to anticipate a claim, the reference must teach every element of the claim.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed.Cir. 1990).

Accordingly, it is most respectfully requested that these rejections be withdrawn in view of the amendments to the claims and the above discussion.

The rejection of claims 27-33 under 35 U.S.C. 103(a) as unpatentable over Eiden et al., Negrevergue and Vidal et al. each taken alone or in combination when similar utilities are asserted has been carefully considered but is most respectfully traversed.

In the Official Action it is urged on page 12, that the indiscriminate selection of "some" among "many" is prima facie obvious citing a 1964 case. In this regard, the

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Examiner's attention is most respectfully directed to MPEP 2144 and the decisions cited therein. As stated therein, The fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a prima facie case of obviousness. In *re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994) ("The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious."); *In re Jones*, 958 F.2d 347, 350, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992) (Federal Circuit has "decline[d] to extract from *Merck [& Co. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir. 1989)] the rule that... regardless of how broad, a disclosure of a chemical genus renders obvious any species that happens to fall within it."). See also *In re Deuel*, 51 F.3d 1552, 1559, 34 USPQ2d 1210, 1215 (Fed. Cir. 1995).

Moreover, the Examiner's attention is most respectfully directed to the basic requirements of a prima facie case of obviousness as set forth in the MPEP § 2143. This section states that to establish a prima facie case of obviousness, three basic criteria first must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In *re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Section 2143.03 states that all claim limitations must be taught or suggested by the prior art. In *re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In *re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In *re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

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Applicants also most respectfully direct the Examiner's attention to MPEP § 2144.08 (page 2100-114) wherein it is stated that Office personnel should consider all rebuttal argument and evidence present by applicant and the citation of *In re Soni* for error in not considering evidence presented in the specification.

The Examiner indicates a belief that the claims of the present application are *prima facie* obvious in view of combinations of Eiden, Negrevergue and Vidal. This is on the basis that the compounds claimed show only activity that might be anticipated from these citations at a predictable level. Applicants believe, however, that the claimed compounds are exceptionally active and in particular are active in ways that could not be anticipated by or suggested any of the cited documents as would be appreciated by one of ordinary skill in the art.

Specifically, Figures 1-5 as filed with the application demonstrate that 4-OH OPB is significantly more active against the HIV virus than the closely related known compound OPB. This small structural change, recited in the main claim, offers an additional therapeutic use of this family of compounds which was neither disclosed nor taught towards by any of Eiden, Negrevergue or Vidal. Furthermore, the 4-hydroxylated compound is surprisingly effective in combination with other antiviral agents. Since neither of these factors were indicated in the prior art, no skilled worker reading that art could expect the observed effects and the structural changes cannot be seen simply as arbitrary because a new and specific use has been disclosed. Applicants thus believe that the enclosed claims are inventive in view of the cited documents. Accordingly, it is most respectfully requested that this rejection be withdrawn.

Applicants note the remarks in connection with the filing of an Information Disclosure Statement in the Official Action. Applicants submit herewith a Form 1449 listing all the references cited in the parent application and include a copy of the International Search Report from the parent application. Applicants request confirmation that the prior art in the parent application, of which this is a continuation application has been considered in the present application. No fee is necessary as these references were cited in the parent application and should also be considered in

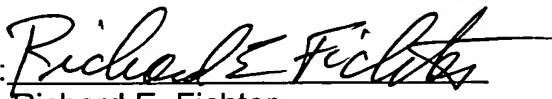
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this application. Accordingly, the Examiner is most respectfully requested to indicate in the next Official Action that these references have been considered and made of record in the present application.

In view of the above comments and further amendments to the claims, favorable reconsideration and allowance of all of the claims now present in the application are most respectfully requested.

Respectfully submitted,

BACON & THOMAS, PLLC

By: 
Richard E. Fichter
Registration No. 26,382

625 Slaters Lane, 4th Fl.
Alexandria, Virginia 22314
Phone: (703) 683-0500
Facsimile: (703) 683-1080

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